REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. This Amendment and Reply to the Final Office Action is being filed within 2 months from the mailing date of the Final Office Action (June 13, 2005) and no extension of time or fee is therefore required.

Claims 1-3, 9-11, and 13-30 were pending in the subject application prior to the filing of this Amendment, with Claim 1 being in independent format. Claim 1 has been amended to specify that the preparation comprising a homeopathic potency of purified insulin-like growth factor-1 suitable for oral administration molar is formulated in a liquid or solid formulation. Claim 3 has consequently been cancelled. Claim 14 has been amended to delete reference to interleukin-1. Claim 20 has been amended to correct a minor typographical error and insert "potency" for "preparation." Claim 29, which previously depended from claim 3 (now canceled) has been amended to depend from independent claim 1.

Claims 24 and 27 have been amended to present the subject matter in independent claim format and to incorporate the subject matter previously recited in independent claim 1. Claims 24 and 27 were indicated by the Examiner to be allowable if rewritten as independent claims. It is therefore urged that independent claims 24 and 27, and claims 25 and 28, which depend from claims 24 and 27, respectively, and were also indicated to be allowable, are now in allowable form.

Claims 1, 2, 9-11 and 13-30 are pending as a result of the amendments presented herein, with claims 1, 24 and 27 presented in independent format.

Applicant notes that the Examiner accepted applicant's previous amendment of the title for the subject specification. Applicant also notes that the Examiner has withdrawn the rejections of Claims 13-15 under 35 U.S.C. §112, second paragraph and the rejection of Claim 5 under 35 U.S.C. §112.

The Examiner has withdrawn rejections of Claims 1-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-13 of U.S. Patent No. 5,629,286. The Examiner has also withdrawn rejections of Claims 1-20 under the

judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-19 of U.S. Patent No. 6,239,105.

Claim Rejection – 35 U.S.C. §112, second paragraph

The Examiner has rejected Claim 26 under 35 U.S.C. §112, second paragraph, as being *indefinite* for failing to particularly point out and distinctly claim the subject matter which applicant regards as her invention. Specifically, the Examiner states it is not clear what a "30C+1M" potency would be. The Examiner suggests that applicant keeps the potency in a single unit such as "C".

The specification and claims employ standardized nomenclature to designate different homeopathic potencies. Homeopathic potencies, also referred to as potency numbers, reflect the number of **dilutions and succussions** from the original mother tincture. There are several accepted methods for preparing homeopathic potencies, each having a separate designation.

The centesimal scale uses the "C" designation and is based upon 100-fold serial dilutions. This is the most commonly used nomenclature. It has become standard practice in the art, however, to adopt Roman numeral designations for certain potencies having large dilution factors. For example, a 1,000C potency is generally referred to as a 1M potency and a 10,000C potency may be denoted 10M. The "C" and "M" designations are necessary to clearly distinguish the homeopathic potency and are used conventionally in the field of homeopathy. It is an accepted principle in homeopathy that each homeopathic potency in a combination of potencies retains its unique "signature" in the carrier medium and combinations of potencies do *not* meld together to create a final potency. Combinations of *potencies* are not simply dilutions of a like substance. Rather, each individual potency in the combination retains its identity and exerts its individual effects. Therefore, it is an accepted practice in homeopathy to designate each potency of the combination in order for homeopathic practitioners to properly distinguish one combination from another.

It is common practice in the marketplace to sell combinations of homeopathic preparations. Attached as Exhibit A are several prints of pages from applicant's Website offering homeopathic products for sale. The "Naturally hGH" product contains recombinant human

Growth Hormone (hGH) in a 6C + 100C + 200C potency. The "Athletic Edge" product contains hGH in a 6X + 12C potency. The "Jenuv Total Body Experience" gel contains hGH in an 8X + 15X + 24X + 6X potency. CSE®-14 Optimal Health Trio contains IGF1, $PDGFF_{BB}$ and TGF_{b1}, all at a 30C + 1M potency. The use of terminology that is conventionally accepted in the field of homeopathy is essential to perform the notice function of patent claims and to properly provide applicant with a basis for excluding others from making, using and selling the claimed compositions. Therefore, applicant respectfully maintains the specification and claims accurately and unambiguously describe the present invention.

Applicant respectfully maintains the nomenclature used in Claim 26 satisfies the requirements of 35 U.S.C. §112, second paragraph by particularly pointing out and distinctly claiming the subject matter of the present invention.

Claim Rejections – 35 U.S.C. §102(b)

The rejection of Claims 1, 9, 10, 14, and 30 (new) under 35 U.S.C. §102(b) as being anticipated by *Antoniades et al.* (U.S. Patent No. 5,035,887) is maintained for reasons indicated in the previous Office Action. This rejection is respectfully traversed, particularly in view of the above amendments and the following remarks.

The Examiner states that applicant's Claim 1, reciting a preparation comprising a homeopathic potency of purified IGF-1 suitable for oral administration, is encompassed by *Antoniades et al.* Specifically, the Examiner states that the pharmaceutically acceptable carriers described in *Antoniades et al.* can also be used for oral administration. In addition, the Examiner states that *Antoniades et al.* encompasses homeopathic potency by using 500ng - 1μg of IGF- and that *Antoniades et al.* teach the inclusion of IGF-1 in a gel which could also be used in a tablet for oral administration.

Antoniades et al. is directed to healing an external wound in a mammal, e.g., a human patient, by applying to the wound an effective amount of a composition that includes a combination of purified PDGF and purified IL-1, or purified IGF-1 and purified IL-1. *See*, Col. 2, lines 10-14. The compositions of *Antoniades et al.* are prepared using a pharmaceutically acceptable carrier substance, e.g. commercially available inert gels, or membranes, or liquids.

See, Col. 2, lines 26-29. The disclosure and teachings of *Antoniades et al.* are directed, exclusively, to the treatment of external wounds, e.g. bed sores and burns, with the combination compositions.

The compositions of *Antoniades et al.* comprise IGF-1 in combination with IL-1 at low concentrations. Applicant's independent claim 1 specifies a preparation having not only a concentration of less than 1 x 10^{-6} molar insulin-like growth factor-1, but it **also requires that the preparation comprise a *homeopathic potency*.** Homeopathic potencies, as evidenced by applicant's specification and the materials of record in the prosecution of this application relating to homeopathy and homeopathic preparations, are made using specialized and standardized techniques involving dilutions and succussions. It is this process, and not merely the highly dilute concentration, that renders a preparation a *homeopathic potency*. There is no teaching or suggestion whatsoever in *Antoniades et al.* that the compositions are prepared homeopathically to produce homeopathic potencies.

There is also no teaching or suggestion of IGF-1 formulated for oral administration, nor would there be any motivation to formulate the compositions of *Antoniades et al.* in a formulation for oral administration for treatment of external wounds. The Examiner argues that one could ingest the gels formulated for topical use in wound healing applications by *Antoniades et al.* orally, and that applicants' claims are thereby anticipated. This strains credulity. Because one *could* ingest a gel intended for topical application to external wounds such as sores and burns does not mean that this reference teaches compositions suitable for oral administration, particularly where the claimed preparation comprises a homeopathic potency suitable for oral administration formulated in a liquid or solid formulation.

The teachings of *Antoniades et al.* do *not* encompass oral formulations and they do *not* encompass homeopathic potencies. Amended claim 1 requires that applicants' claimed preparation comprising a *homeopathic potency* of purified insulin-like growth factor-1 is suitable for *oral administration*, and that it is *formulated in a liquid or solid formulation*. It is urged that applicant's pending claims are ***not*** anticipated by *Antoniades et al*, and that the rejection of the claims under 35 U.S.C. §102(b) must be withdrawn.

Claim Rejections – 35 U.S.C. §103(a)

The rejection of Claims 13, 15-18, and 21-23 (new) under 35 U.S.C. §103(a) as being unpatentable over *Antoniades et al.*, in view of *Vithoulkas et al.* was maintained. This rejection is respectfully traversed, particularly in view of the above amendments and the following remarks.

The teachings of *Antoniades et al.* and the deficiencies of *Antoniades et al.* with respect to applicant's claims are discussed above. *Vithoulkas et al.* describes standard protocols and nomenclatures for homeopathic potencies. *Vithoulkas et al.* does not overcome the deficiencies of *Antoniades et al.* with respect to applicant's claimed preparations. Applicant does not discern any teaching or suggestion in *Antoniades et al.* or *Vithoulkas et al.*, or any combination of those references, that would anticipate or render obvious applicant's claimed preparation comprising a homeopathic potency of purified IGF-1 suitable for oral administration that is formulated in a liquid or solid formulation, nor does applicant discern any motivation for combining the teachings of these references.

The rejection of Claims 2, 3, 11, 20, and 29 under 35 U.S.C. §103(a) as being unpatentable over *Antoniades et al.*, in view of *Clark et al.* (U.S. Patent No. 5,597,797) is maintained. This rejection is respectfully traversed, particularly in view of the above amendments and the following remarks.

The teachings of *Antoniades et al.* and the deficiencies of *Antoniades et al.* with respect to applicant's claims are discussed above. *Clark et al.* discloses methods for treating obesity by administering an effective amount of growth hormone (GH) in combination with an effective amount of IGF-1. GH administration is by continuous infusion (using, e.g., an osmotic pump) or by injections more frequent than once a day and may be administered in a form in which it is bonded to a polymer. Similar administrations of IGF-1 are described. The dose for each component is on the order of micrograms to milligrams/kg body weight/day. These dosages are ***not*** at the concentrations set out in applicant's claims, nor is there any indication that the dosages are prepared homeopathically as would be required to produce homeopathic potencies. Applicant also does not perceive that *Clark et al.* discloses or suggests oral administration of the

combination. It is therefore urged that applicant's pending claims are *not* rendered obvious in view of this combination of references.

The rejection of Claim 19 under 35 U.S.C. §103(a) as being unpatentable over *Antoniades et al.*, in view of *Whitson-Fischman* (U.S. Patent No. 5,162,037) is maintained. This rejection is respectfully traversed.

The teachings of *Antoniades et al.* and the deficiencies of *Antoniades et al.* with respect to applicant's claims are discussed above. *Whitson-Fischman* discloses magnetizing homeopathic mixtures of herbs, herbal extracts and other compounds and administering such homeopathic medicaments through selected acupuncture points. Various delivery forms of homeopathic preparations are described. Applicant does not perceive that *Whitson-Fischman* discloses or suggests the use of homeopathic potencies of purified IGF-1 or other purified growth factors. *Whitson-Fischman*, rather, discloses the use of more conventional herb-based homeopathic medicaments.

It is urged that *Whitson-Fischman* does not overcome the deficiencies of *Antoniades et al.* with respect to applicant's pending claims and that no combination of the references relied upon for rejection renders applicant's claimed preparations obvious in the manner required by 35 U.S.C. §103(a).

Claim Objections

Claims 24, 25, 27, and 28 were objected to for being dependent on rejected Claim 1. Applicant notes that the Examiner states these claims would be allowable over prior art if they are written as independent claims. Claims 24 and 27 have been rewritten in independent format and it is therefore urged that claims 24, 25, 27 and 28 are in allowable form.

Conclusion

In view of the above amendments and remarks, applicant believes that all of the pending claims are now in condition for allowance. Early consideration and allowance of all the pending claims is respectfully requested.

Respectfully submitted,

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Date: August 15, 2005

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EXHIBIT A